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United States General Accounting Office  
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B-292561

July 21, 2003

The Honorable Thad Cochran  
Chairman  
The Honorable Tom Harkin  
Ranking Minority Member  
Committee on Agriculture, Nutrition, and Forestry  
United States Senate

The Honorable Bob Goodlatte  
Chairman  
The Honorable Charles W. Stenholm  
Ranking Minority Member  
Committee on Agriculture  
House of Representatives

Subject: *Department of Agriculture, Food Safety and Inspection Service: Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Agriculture, Food Safety and Inspection Service (FSIS), entitled "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products" (RIN: 0583-AC46). We received the rule on July 7, 2003. It was published in the Federal Register as an interim final rule on June 6, 2003. 68 Fed. Reg. 34208.

The interim final rule amends FSIS's regulations to require official establishments that produce certain ready-to-eat (RTE) meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes* (*L. monocytogenes*).

Enclosed is our assessment of the FSIS's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review indicates that the FSIS complied with the applicable requirements

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation work relating to the subject matter of the rule is Robert Robinson,

Managing Director, Natural Resources and Environment. Mr. Robinson can be reached at (202) 512-3841.

signed

Kathleen E. Wannisky  
Managing Associate General Counsel

Enclosure

cc: Garry L. McKee, Ph.D., M.P.H.  
Administrator, Food Safety and  
Inspection Service  
Department of Agriculture

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE  
ISSUED BY THE  
DEPARTMENT OF AGRICULTURE,  
FOOD SAFETY AND INSPECTION SERVICE  
ENTITLED  
"CONTROL OF *LISTERIA MONOCYTOGENES* IN  
READY-TO-EAT MEAT AND POULTRY PRODUCTS"  
(RIN: 0583-AC46)

(i) Cost-benefit analysis

The Food Safety and Inspection Service performed a cost-benefit analysis of the interim final rule. The industry-wide annualized cost is \$16.6 million. With a 50-percent downward adjustment to correct for what FSIS believes may be an overstatement of the benefits, the interim final rule is estimated to produce net benefits of \$50.8 million at the median and ranging from \$5.4 million at the 5<sup>th</sup> percentile to \$60.4 million at the 95<sup>th</sup> percentile.

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603-605, 607, and 609

The FSIS prepared a Final Regulatory Flexibility Analysis in connection with the interim final rule, which is contained in Appendix A to the rule. The analysis complies with the requirements of the Regulatory Flexibility Act and includes the need for the rule, the number and size of the small entities affected by the rule, and the alternatives considered to minimize the impact on the small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

The interim final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, of more than \$100 million in any one year.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

The interim final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On February 27, 2001, the FSIS published a Notice of Proposed Rulemaking in the Federal Register. 66 Fed. Reg. 12590. After extending the comment period twice, FSIS received 28 comments in response, and the comments are discussed in the preamble to the interim final rule.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

The interim final rule contains an information collection that is subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. FSIS has submitted the required information regarding the collection to OMB, including the estimated annual burden of 154,243 hours.

Statutory authorization for the rule

The interim final rule is issued pursuant to 7 U.S.C. 450, 7 U.S.C. 1901-1906, and 21 U.S.C. 451-470 and 601-695.

Executive Order No. 12866

The interim final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the order.